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EXAMINER

HUPCZEY, JR, RONALD JAMES

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,297	Applicant(s) SCHNITZLER ET AL.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9-17, 19 and 21 is/are rejected.
- 7) ☐ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks, filed March 1st, 2010, are acknowledged. Currently, claims 1-3 and 5-17 and 19-21 are pending with claim 9 and 19-20 amended and claims 4 and 18 cancelled. The following is a complete response to the March 1st, 2010 communication.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5-7 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosmescu (US Pat. No. 6,149,648).

Regarding claim 1, Cosmescu discloses an apparatus for coagulating tissue (as best seen in figures 6-6C and 8A) comprising an electrode capable of producing a high-frequency current (electrode **112** or electrode **436**), a gas-delivering device (tube **152** or exhaust port **416** connected with tube through body of device of figure 8A) having an outlet (distal flared end at **154** or exhaust opening **424**) and being capable of delivering an inert gas from said outlet into a space defined between said electrode and said tissue (see spaces defined in each of figures 6-6C and figure 8), such that a plasma is produced between said electrode and said tissue when said high frequency current is applied to said inert gas (such functionality would be provided if inert gas was so supplied in either embodiment of figures 6-6C or 8), wherein a distal end of said electrode projects out of said gas-delivering device (electrodes **112** and **406** extending as in figures 5 and 8) and a guiding device disposed at said distal end of said electrode (enlarged portion of each of the electrodes **112** and **406** as shown in the figures) wherein the guiding

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device is capable of guiding and directing at least one of the gas and the plasma such that at least a part of said gas and plasma is diverted in a predetermined direction (enlarged portion of the electrodes **112** and **406** effect the directly flow of gas in a predetermined manner). It is noted that such language as “adapted to” and “for” which has been recited above is seen as a recitation of intended use. It has been held that a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 3, Cosmescu discloses that the guiding device is comprised of a thermally stable material (electrode **112** and **406** being construction from a thermally stable material as in col. 13; 23 - col. 15; 5).

Regarding claim 5, Cosmescu discloses that the guiding device functions such that supplied gas would flow into said space substantially radially with respect to said outlet of said gas-delivering device (gas exiting at flared area of flange **154** or from exhaust opening **424** into a radial space due to enlarged portion of electrode **112** or **406**).

Regarding claim 6, Cosmescu discloses that the guiding device (electrode **112** in figure 6A) has a concave configuration on a side thereof that faces said outlet (the step from the reduced diameter portion to the enlarged diameter portion displays a concave arrangement which faces the opening defined by the flared end at **154**).

Regarding claim 7, Cosmescu disclose that the guiding device has a contour which prevents mechanical damage if said guiding device touches said tissue (rounded outer

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configuration of electrode **112** or **406** and the ball shape of the interchangeable electrode in figure 8D).

Regarding claim 21, Cosmescu discloses that the guiding device has a rounded contour (rounded outer configuration of electrode **112** or **406** and the ball shape of the interchangeable electrode in figure 8D).

Claim Rejections - 35 USC § 103

3. Claims 2, 9-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmescu (US Pat. No. 6,149,648) in view of La Fontaine et al (US Pat. No. 5,902,328).

Regarding claim 2, Cosmescu fails to disclose that the guiding device is comprised of an electrically insulating material. LaFontaine discloses a similar device which is capable of functioning for the intended use of the instant device of claim 1. LaFontaine shows that the device contains an electrode (electrode **102**) with a guiding device located at the distal end thereon (deflecting body **100**) which directs a supply from a delivery tube (tube **32** with flow indicated by arrows in figure 7). LaFontaine further discloses the guiding device to be comprised of an electrically insulating material (see col. 17; 5-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an electrically insulating enlarged portion to the electrodes **112** and **406** of Cosmescu to provide for combined device such as in claim 2. The provision of the electrically insulating guiding device would, as taught by LaFontaine, would ensure that energy would only be transferred to the fluid/gas which is passed on the electrode such that direct energy transmission to tissue which may come into contact with the guiding device would not occur. This would reduce the chance of penetration,

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charring or burning of the treatment area as well as reducing or eliminating the build-up of coagulum on the electrode during treatment.

Regarding claim 9, Cosmescu disclose an apparatus for coagulating tissue comprising a gas-delivering device (device in figures 5-6C with tube **152** or device of figure 8 with exhaust opening **424**), an electrode disposed substantially coaxially with the gas-delivering device and configured to generate a high-frequency current (electrode **112** or electrode **406/436** wherein a distal end of the electrode projects outward through an outlet of the gas-delivering device (see figures 5-6C and figure 8) and a guiding device disposed at the distal end of the electrode (enlarged portion of each of the electrodes **112** and **406/436**) wherein the guiding device is configured for guiding an inert gas stream flowing through the gas-delivering device (enlarged portion of each of the electrodes would effect the direction of the flow of gas over the electrode). Cosmescu fails to disclose that the guiding device is comprised of a material that is electrically insulating and thermally stable. LaFontaine discloses a similar device which is capable of functioning for the intended use of the instant device of claim 1. LaFontaine shows that the device contains and electrode (electrode **102**) with a guiding device located at the distal end thereon (deflecting body **100**) which directs a supply from a delivery tube (tube **32** with flow indicated by arrows in figure 7). LaFontaine further discloses the guiding device to be comprised of an electrically insulating material (see col. 17; 5-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an electrically insulating enlarged portion to the electrodes **112** and **406** of Cosmescu to provide for combined device such as in claim 2. The provision of the electrically insulating guiding device would, as taught by LaFontaine, would ensure that energy would only be transferred to the fluid/gas which

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is passed on the electrode such that direct energy transmission to tissue which may come into contact with the guiding device would not occur. This would reduce the chance of penetration, charring or burning of the treatment area as well as reducing or eliminating the build-up of coagulum on the electrode during treatment.

Regarding claim 10, Cosmescu discloses that the guiding device is disposed in an axially symmetric manner around the distal end of the electrode (see disposition of guiding devices described in claim 9 above in figures 6A and 8).

Regarding claim 11, Cosmescu discloses that the guiding device is configured such that the inert gas stream is guided into a surrounding space substantially radially with respect to the outlet of the gas delivering device (gas exiting at flared area of flange **154** or from exhaust opening **424** into a radial space due to enlarged portion of electrode **112** or **406**).

Regarding claim 12, Cosmescu discloses that the guiding device is shaped such that damage to the tissue is prevented if the guiding device touches the tissue (rounded outer configuration of electrode **112** or **406** and the ball shape of the interchangeable electrode in figure 8D).

Regarding claim 13, Cosmescu discloses that the guiding device is spherical (see shape of electrode **440** in figure 8D which is interchangeable into the device of Figure 8A).

Regarding claim 14, Cosmescu discloses that the guiding device comprises a concave surface at a surface facing the outlet of the gas-delivering device (the step from the reduced diameter portion to the enlarged diameter portion displays a concave arrangement which faces the opening defined by the flared end at **154**) and a flattened surface at a surface facing away from the outlet of the gas-delivering device (flattened surfaces from outermost point on electrode

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112 to tip of electrode **112** and facing away from the outlet at **154**) and wherein a transitional region between the concave surface and the flattened surface has a rounded contour (the rounded outer shape of electrode **112** disclosed in figure 6A such that it fits within the tube **154** as shown in figure 7A which is between the stepped portion and the tip portion).

Regarding claim 15, Cosmescu discloses that the guiding device comprises a concave surface at a surface facing the outlet of the gas-delivering device (the step from the reduced diameter portion to the enlarged diameter portion displays a concave arrangement which faces the opening defined by the flared end at **154**) and a substantially hemispherical surface at a surface facing away from the outlet of the gas- delivering device (taken in totality, the flattened portion of each side of electrode **112** from the outermost point at each side of the electrode to the tip has a substantially hemispherical shape).

Regarding claim 16, Cosmescu discloses that the electrode is configured such that it may be retracted and pushed forward with respect to the gas-delivering device (see col. 13; 27- col. 15; 5).

Regarding claim 17, Cosmescu discloses that when the electrode is in a fully retracted state, the guiding device is seated on the outlet of the gas-delivering device (outermost diameter in relation to the interior of tube **154** when electrode is retracted as in col. 13; 27 – col. 15; 5). The Examiner notes that the limitation of "seated on" is not being interpreted as requiring the "substantially leakproof" arrangement found in other pending claims and in the instant case, the electrode is being considered seated on when at least a portion of the electrode is in some degree of contact with the outlet.

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Regarding claim 19, both Cosmescu and Lafontaine fail to disclose that the guiding device is comprised of a ceramic. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a ceramic material in place of the disclosed insulative material of LaFontaine since it has been held to be within the purview of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Additionally, Applicant has failed to set forth any criticality or unexpected results which would render the use of a ceramic material as a non-obvious design variation.

Allowable Subject Matter

4. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claim 20 is allowed.

6. The following is a statement of reasons for the indication of allowable subject matter: During the search of the prior art, Cosmescu and LaFontaine were identified as the closest prior art of record to the instant device described in each of claims 8 and 20. While Cosmescu and LaFontaine each disclose a plurality of the structural and functional limitations of the instant invention, neither whether alone or in combination disclose an arrangement where the “electrode is movable relative to said outlet such that when said electrode is moved into a retracted position, said guiding device closes said outlet in a substantially leakproof manner”. While the electrodes **112** and **406/436** of Cosmescu are moveable as set forth in column 13 through column 15, Cosmescu specifically sets forth that the retracted position of the electrode still allows for gas to

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be directed past the electrode/guiding device. LaFontaine, while displaying a guiding device which is clearly larger than the outlet of the gas delivering device, does not disclose nor provides motivation for the electrode/guiding device combination to be movable in relation to the outlet or to seal the outlet. For at least the above reasoning, the Examiner believes that the subject matter of claims 8 and 20 distinguish over the prior art of record.

Response to Arguments

7. Applicant's arguments, see pages 9-11, filed March 1st, 2010, with respect to the rejections of claims 8 and 20 have been fully considered and are persuasive. The rejection of October 18th, 2009 has been withdrawn.

Specifically, Applicant has persuasively argued the limitation of the electrode, guiding device and outlet providing a substantially leakproof arrangement when the electrode and guiding device are fully retracted.

8. Applicant's arguments filed March 1st, 2010 have been fully considered but they are not persuasive.

In response to Applicant's argument on page 7 of the Remarks regarding the applicability of the Cosmescu's figure 8 embodiment over claim 1, the Examiner respectfully disagrees. In considering the claim language in claim 1 again, Applicant has stated that the gas-delivering device has an outlet and is "***adapted to deliver and inert gas from said outlet***". As noted in the rejection of claim 1 above, it has been held that language such as "adapted to" and "for" impart recitations of intended use and it has been held that a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure

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is capable of performing the intended use, then it meets the claim. While the desired function of the device of figure 8 of Cosmescu may be a smoke evacuator, the structure and functional limitations of claim 1 are met by the embodiment. It is the Examiner's position that if the smoke evacuator were attached to a source of inert gas instead of a source of suction, the device would be capable of functioning as claimed in the "adapted to" portion of claim 1. Additionally, it is noted that Applicant has not positively recited or tied the device of claim 1 to a source of inert gas. Therefore, it is the Examiner's position that for at least the above reasoning the embodiment of figure 8 of Cosmescu still reads on claim 1.

In response to Applicant's argument on pages 7-8 of the remarks that the electrode of Cosmescu is not of the shape characterized by the Examiner in the rejection of claim 1 above, the Examiner respectfully disagrees. The Examiner has carefully considered Applicant's submitted drawings and alleged explanation of the cross-sectional and side view of electrode **112** of Cosmescu. However, the Examiner has not found valid reasoning in pages 7 or 8 which persuasively shows that Applicant's interpretation of the shape is the true shape of the electrode so as to overcome the Examiner's interpretation. While Applicant has stated that the side view is a view which is rotated 90 degrees from the cross sectional view, nowhere does the Examiner find support for such a claim. Applicant's limited labeling and explanation of the figures on page 8 also does little to support this claim. The Examiner maintains that the shape of the electrode in 6A is as characterized in the rejections above. The Examiner respectfully believes that Applicant is confusing the socket **108** and its shape as shown in figure 7C with its vanes **107** as the shape of a portion of the electrode which shows the "cross" or "plus-sign" shape characterized in Applicant's figure 3 on page 8 of the Remarks. In the instance that the electrode **112** of

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Cosmescu was a shape other than that characterized by the Examiner, the Examiner would still consider any enlarged portion (cross-shaped, spatula-shaped, etc) as a guiding device which due to its enlarged cross-section in a least one direction, would be capable of directing gas flowed over it in a predetermined direction. It is therefore the Examiner's position that the rejection of claim 1 by Cosmescu remains tenable.

In response to Applicant's argument on pages 8-9 of the Remarks that the combination in claim 9 of Cosmescu and LaFontaine is improper, the Examiner respectfully disagrees. The Examiner would first like to note the interpretation set forth in claim 1 and the remarks above referencing the intended use recitations in claim 1. Like claim 1, claim 9 is being interpreted by the Examiner as having recitations of intended use by only stating a "gas-delivering device". Since this is not tied to a source of gas nor has only other structure recited, the Examiner is interpreting the "gas-delivering device" as only needing to be capable of delivering gas. Both the embodiments of Cosmescu are seen as being capable as well as the device of LaFontaine which is disclosed as delivering a fluid. In light of this characterization, the Examiner believes that one of ordinary skill in the art would appreciate the provision of an electrically insulating guiding device so as to not directly pass electrical energy to the tissue thereby reducing on the chance of pitting (as displayed in figure 7 of LaFontaine) as well as the reduced chance of charring or burning the tissue or coagulum buildup on the electrode. While Cosmescu does disclose functionality of the device in a cutting mode which directly passes energy to the tissue, Cosmescu does also disclose the removability of the electrode and the desire to use the device in only an argon-plasma mode which would lend itself well to not passing energy directly to the tissue. It is therefore for at least this reasoning above that the Examiner believes that the

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combination of Cosmescu and Lafontaine is proper and as such, the Examiner has maintained these rejections above.

In response to the remainder of the arguments, the Examiner respectfully disagrees. To the argument addressing claims 2 and 6, the Examiner has pointed out above why the combination of Cosmescu and LaFontaine is believed to be proper. Additionally, with respect to claim 6, the Examiner has proffered a new interpretation of Cosmescu to address the limitation therein. With regard to the argument addressing claims 14, 15 and 19, it is noted that Applicant's claims 14 and 15 are quite broad when specifying which portions of the electrodes are of what shape. The Examiner has clarified in the rejections above which portions of the electrode **112** is believed to read on each shape. Additionally, the Examiner notes that the term "flattened" is not believed to require the surface to be perfectly flat but rather have less of a curved surface in relation to another part of the electrode. It is for at least this reasoning and the interpretations presented in the rejections of the claims that the Examiner believes the rejections remain tenable.

Conclusion

9. In light of Applicant's persuasive arguing, this action has been made ***NON-FINAL***.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH